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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,739	11/08/2001	James C. Copeland	OXR 2 0025	4971

7590 10/16/2003

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

	Application No.	Applicant(s)
Office Action Summary	10/007,739	Copeland et al
	Examiner: Portner	Art Unit: 1645

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 8, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-35 are pending.

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed April 9, 2002 has been considered.

35 U.S.C. § 112

3.The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3,6, 8-9, 26, 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a medium for the selective enhancement of anaerobes from a mixed sample that only contains facultative microorganisms. The invention is not distinctly claimed in light of the sample being defined to "contain facultative microorganisms". Other organisms that could be mixed with the facultative bacteria are aerobic, micro-aerophilc, and strict anaerobes.

Claim 2 recites the phrase "broth medium"; the term "broth" lacks antecedent basis in claim 1 from which it depends.

Claim 3 recites the phrase "agar medium"; the term "agar" lacks antecedent basis in claim 1 from which it depends.

Claim 6 recites a "wherein" clause; it should be amended to recite the phrase --further comprises--, as claim 1 from which claim 6 depends does not comprise "an oxygen reducing agent".

Claim 8, paragraph b recites the phrase "a sample"; this phrase does not define the sample to be the "mixed samples" of the preamble; the invention is not distinctly claimed. Amendment of the claim to recite the definite article --the-- could obviate this rejection.

Claim 8, paragraph e) recites the phrase "sampling the medium composition containing the azide for further characterization and isolation of the anaerobe organism". Paragraph e) further characterizes the medium, and not bacterial growth in the medium. Only one medium composition was provided in paragraph a); how can two mediums be compared in paragraph d) when only one medium has been provided. The invention is not distinctly claimed.

Regarding claim 9, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). How do the "means" and "medium" composition" correspond one to the other in the claimed device?

Claim 26 recites the phrase "sufficient to limit the growth" and depends from claim 25 which recites the phrase "restricts the growth"; both phrases recite relative terms, without reference to any specific level of growth or non-growth. Claim 26 is broader in scope than claim 25, in that the medium must only limit the growth to any amount and the medium of claim 25 must restrict the growth of facultative microbes. Claim 26 is not further limiting of claim 25. Clarification is requested.

Claim 28 is directed to a method of selective growth and isolation of an anaerobic microbe, but the claim does not recite an "isolation" step; only inoculating and incubating

steps. The combination of claim limitations does not distinctly claim Applicant's invention, nor do the combination of claim limitations correlate with the recited intended use set forth in the preamble of the claim.

Claim 29 depends from claim 28 and recites three additional methods steps of providing, inoculating and incubating, wherein the plate agar of claim 29 is inoculated with the medium composition containing the mixed sample. It appear that the method of claim 29 excludes step c. of claim 28 by taking the sample from the medium of step 28 b.. Claim 29 is confusing as it depends from claim 28, and therefore recites all of the claim limitations of claim 28, but does not carry out the methods step of claim 28c. Clarification of the methods steps of claim 29 is requested. Claim 29, like claim 28, also does not isolate an anaerobe; the recited method steps do not correlate with the recited preamble of the claim.

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1,3-5,7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Merad et al (1992).

(Claim 1) Merad et al disclose the instantly claimed invention directed to a medium composition that comprises a nutrient medium and a salt of an azide (see Columbia agar), wherein the azide is sodium azide.

The medium functioned to limit the growth of facultative anaerobe microorganisms, and to enhance the isolation of strictly anaerobic bacteria in a mixed sample (polymicrobial mixture). (See abstract, title, page 163, materials, page 165, Table at bottom of page; page 166, section labeled "3-" with respect to action of various inhibitors at various concentrations.)

Instant claim 3: agar (see abstract), azide range including 1.0 mg/ml (see page 165, "2-", col. 4, in table shown at bottom of page).

Instant claim 4: nutrient agar (Columbia agar is a type of nutrient agar).

Instant claim 5: medium contained in an anaerobic chamber, jar or bag (see page 164, lines 6-9, Jarre pour anaerobie avec sachets Gaz-Pack, and Anaerocult P (sachet individuel pour anaerobisose").

Instant claim 7: wherein the mixed sample is obtained from infections (see page 162, paragraph 3 "encounted in the infections") which would include patients, economically important animal or pharmaceutical sample ("samples we receive in the laboratory", see page 162, paragraph 4).

Instant claim 8: Merad et al disclose a method of isolating an anaerobic microorganism from a mixed sample containing facultative microorganisms, the method comprising the steps of:

providing medium that comprises azide (see page 163, last line and page 164, paragraphs 2-3 (trypticase yeast enrichid'Hamine and gelose columbia);

inoculating a sample into the medium composition (see page 164, paragraphs 7-10; "L'isolement des souches anaerobies strictes seules, est ensuite pratique sure 3 boites de Petri contenant" and "l'isolemnet a partir de ce melange est realise de la meme maniere que celui des anaerobies stricts seuls c'est a dire sur 3 boites contenant chacune l'un des 3 inhibiteurs");

incubating the inoculated medium composition anaerobically (see page 164, last paragraph (37°C en anaerobiose, 24h a 48h);

comparing the growth in the medium composition with partial growth with the azide being indicative that an anaerobe is present (comparison between no growth and heavy growth (see page 165, paragraph 2-, complete table compared with the action of the inhibitors, see page 166, paragraph 3-);

sampling the medium composition containing the azide for further characterization and isolation of the anaerobe organism (analysis of the bacteria present in the azide medium was evaluated to be very very good (mauvais resultat, page 166, table 3-) or very good (tres bon resultat, page 166, table 3-) and the results determined (see page 167, all paragraphs at top of page "Les resultants)

Instant claim 9: A combination of means for creating an anaerobic environment (Gas-Pack, Jarre pour anaerobie avec sachets; and Anaerocult P (sachet individual pour anaerobiose) together with media that comprises an inhibitor of facultative anaerobic growth is disclosed (see page 164, paragraphs 9-10, last two paragraphs on page 164, as well as paragraphs 3-5 at top of page 164; see page 163, last paragraph (Azide de sodium Fluka (Az Na).The reference anticipates the instantly claimed invention.

7. Claims 1-2,4-5, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al (1984).

(Claim 1) Jones et al disclose the instantly claimed invention directed to a medium composition that comprises a nutrient medium and a salt of an azide (see TYG broth with..azide,

see page 99, Table 2, top of page), wherein the azide is sodium azide (see page 97, ledger for Figure 1, "sodium azide").

The medium functioned to limit the growth of facultative anaerobe microorganisms (anaerobic growth of a facultative anaerobe was totally inhibited by 1mM azide, see page 95, center of abstract).

Instant claim 2: broth medium within recited range of azide (see page 99, Table 2, all data and ledger narrative).

Instant claim 4: nutrient broth TYG, tryptone/yeast extract/glucose (see page 96, paragraphs 1-2).

Instant claim 5: wherein the medium is contained in an anaerobic jar (see page 96, paragraph 2 "Tubes were incubated in an anaerobic jar").

Instant claim 9: the composition of a medium comprising limited nutrients and a means for creating an anaerobic environment is disclosed (see Table 2, page 99, all information and Methods section page 96, paragraphs 1-2). The reference anticipates the instantly claimed invention.

8. Claims 10-12, 15-17, 20, 22 are rejected under 35 U.S.C. 102(b) as being anticipate by Blondin et al (US Pat. 4,808,517).

(Instant claim 10 and 20) Blondin et al disclose a medium composition that comprises a microbiological nutrient medium comprising (see col. 6, lines 3-42):

a hydrogen donating substance (see col. 6, line 6 and 14: tris-chloride buffer, sucrose and **succinate**);

an electron transport system (**mitochondrial preparation**, col. 6, line 3); and

an inhibitor of cellular respiration (see col. 6, lines 20-22: **antimycin**; col. 6, line 39, **cyanide**). The reference anticipates the instantly claimed invention.

Instant claim 11:organic substrate (succrose and succinate, col. 6, line 6 and 14);

Instant claim 12: succinic acid or corresponding salt (succinate, col. 6, line 14);

Instant claim 15:oxygen scavenging membrane fragments derived from membranes of non-bacterial mitochondrial organelles (mitochondrial preparation, see col. 3, lines 65-68, col. 4, lines 1-24; col 4, lines 54-68; col. 6, line 3);

Instant claims 16-17, 22: cyanide combined with other ingredients (see col. 6, lines 34-39).

The recited intended use of the claimed medium composition does not define over the prior art. Blondin et al anticipates the instantly claimed invention.

9. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Tillonen et al (1998).

Tillonen et al disclose a medium composition that comprises a base medium (potassium phosphate (KPO) buffer pH7.4 (see page 1114, col. 1, paragraph 5) together with a biocatalytic oxygen reducing agent (glucose oxidase is defined to be a biocatalytic oxygen reducing agent, see Instant Specification page 14, paragraph 1; Tillonen et al page 1114, col. 2, paragraph 1, middle of paragraph), and a salt of an azide (see Tillonen et al, page 1114, col. 1, paragraph 5 and col. 2, paragraph 1, (SA= sodium azide); also see Figure 4, Tillonen et al, page 1115; also see page 116, paragraphs 2 and 3). The reference anticipates the instantly claimed invention.

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224).

Merad et al disclose a medium composition that comprises a nutrient medium (Columbia agar), together with an inhibitor of an electron transport system required for cellular respiration for the purpose of isolating anaerobic microorganisms from a mixed sample. Merad et al differs from the instantly claimed invention by failing to show the utilization of a hydrogen donating substance together with a plurality of oxygen scavenging membrane fragments.

Adler shows a medium composition (nutrient broth (see col. 4, line 5) or nutrient agar (see col. 5, lines 8-10), that may be liquid (see col. 2, lines 66-68) or solid ((see col. 3, lines 23-25), that comprises a hydrogen donating (see col. 5, lines 30-37) substance (lactate , succinate, formate or glycerol phosphate; see col. 6, claims 5 and 8) together with a plurality of oxygen scavenging membrane fragments (membrane fragments isolated from E.coli, Salmonella typhimurium, Gluconobacter oxydans or Pseudomonas aeruginosa (see Example IV, col. 5, lines 17-29; see claims 3-4) in an analogous art for the purpose of isolating anaerobic microorganisms (see all claims, especially claims 1 and 9) from patients, formulation of a transport medium for samples from the patient to the laboratory (see col. 5, lines 63-64), for fermentation processes (medium contained in anaerobic chamber, see col. 6, line 2) and for further analysis of anaerobic bacteria for antibiotic sensitivity (see col. 5, line 65; col. 6, lines 1-10)

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the medium of Merad et al together with the medium of Adler to obtain a third composition for isolating anaerobic microorganisms because it is "prima facie

obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose: idea of combining flows logically from their having been individually taught in the prior art" In re Kerkhoven (205 USPQ 1069, CCPA 1980).

12. Claims 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merad et al (1992) in view of Adler (US Pat. 4,476,224).

Merad et al teach a method of isolating an anaerobic microorganism from a mixed sample containing facultative microorganisms, the method comprising the steps of:

providing agar based medium that comprises azide (see page 163, last line and page 164, paragraphs 2-3 (trypticase yeast enrichid'Hamine and gelose columbia);

inoculating a mixed sample into the medium composition (see page 164, paragraphs 7-10; "L'isolement des souches anaerobies strictes seules, est ensuite pratique sure 3 boites de Petri contenant" and "l'isolemnet a partir de ce melange est realise de la meme maniere que celui des anaerobies stricts seuls c'est a dire sur 3 boites contenant chacune l'un des 3 inhibiteurs");

incubating the inoculated medium composition anaerobically (see page 164, last paragraph (37°C en anaerobiose, 24h a 48h);

comparing the growth in the medium composition with partial growth with the azide (would further comprise the steps of providing, innoculating and incubating a strain of bacteria for comparison) being indicative that an anaerobe is present (comparison between no growth and heavy growth (see page 165, paragraph 2-, complete table compared with the action of the inhibitors, see page 166, paragraph 3-);

sampling the medium composition containing the azide for further characterization and isolation of the anaerobe organism (analysis of the bacteria present in the azide medium was evaluated to be very very good (mauvais resultat, page 166, table 3-) or very good (tres bon resultat, page 166, table 3-) and the results determined (see page 167, all paragraphs at top of page "Les resultants)

Merad et al teaches a method of isolating an anaerobe from a mixed sample, the method utilizing a medium composition that comprises a nutrient medium (Columbia agar), together with an inhibitor of an electron transport system required for cellular respiration for the purpose of isolating anaerobic microorganisms from a mixed sample. The method of Merad et al differs from the instantly claimed invention by failing to show the medium composition to comprise a hydrogen donating substance together with a plurality of oxygen scavenging membrane fragments.

Adler teaches a method of isolating an anaerobe utilizing either an broth or agar based medium composition (nutrient broth,see col. 4, line 5, see col. 2, lines 66-68); nutrient agar, see col. 5, lines 8-10, see col. 3, lines 23-25), that comprises a hydrogen donating (see col. 5, lines 30-37) substance (lactate , succinate, formate or glycerol phosphate; see col. 6, claims 5 and 8) together with a plurality of oxygen scavenging membrane fragments (membrane fragments isolated from E.coli, Salmonella typhimurium, Gluconobacter oxydans or Pseudomonas aeruginosa, see Example IV, col. 5, lines 17-29; see claims 3-4) in an analogous art for the purpose of showing a method of isolating anaerobic microorganisms (see all claims, especially claims 1 and 9) from patients, formulation of a transport medium for samples from the patient to `the laboratory (see col. 5, lines 63-64), for fermentation processes (medium contained in anaerobic chamber, see col. 6, line 2) and for further analysis of anaerobic bacteria for antibiotic

sensitivity (see col. 5, line 65; col. 6, lines 1-10), wherein growth of anaerobic bacteria is promoted and improved over other methods (see Alder, col. 1, lines 8-12; improved, see col. 1, lines 54-55).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of Merad et al to include the medium components of Adler, because both Merad and Adler teach methods of isolating anaerobic bacteria through the utilization of a selective anaerobic growth medium and it is "prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose: idea of combining flows logically from their having been individually taught in the prior art" In re Kerkhoven (205 USPQ 1069, CCPA 1980).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. US Pat. 6,376,211, Example 3B, cols 25-26 is cited to show a combination of E.coli bacterial membranes, with XMP.391, an inhibitor of ATP synthesis, in a buffer solution containing HCL, EDTA, glycerol

15. US Pat. 4,485,016 is cited to show a composition of alcohol or glucose oxidase, glucose and aside .

16. US Pat. 3721607 is cited to show a media composition that comprises glucose oxidase, a buffer (hydrogen donator), an azide and sulfonic acid.

17. USPat. 6,485,947 is cited to show an anaerobic growth medium that comprises azide, cyanide or antimycin A; all inhibitors of cellular respiration.

18. USPat. 6,153,400 is cited to show anaerobic growth medias known in the art (see claim 38), as well as azide blood agar which is considered to be a selective media (see claim 34).

19. Kone, K et al (1994, abstract P-20) is cited to show the growth of strict anaerobes under aerobic conditions in the presence of Oxyrase (E.coli membrane fraction containing oxygen scavenging enzymes).

20. Pratt, K et al (1992, abstract C-366) is cited to show Oxyrase supplemented broth media for the growth of anaerobe bacteria.
21. Spangler et al (1995) is cited to show oxydish plate and lid system for the growth and evaluation of anaerobes.
22. Wiggs et al (2000) is cited to show the evaluation of anaerobic growth of various genera of bacteria using Oxyrase oxyplates.
23. Wong, PCK, (1997, abstract) is cited to show the recovery and toxin production of Clostridium botulinum in Oxyrase supplemented culture media.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
October 8, 2003

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